REMARKS

Applicants respectfully request entry of the foregoing and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, and in light of the remarks that follow.

Claims 5-14, 16-25, 27-37 and 39-46 are pending in the application, claims 1-4, 15, 26 and 38 having been canceled above and new claims 39-47 having been added.

By the above amendments, claims 5, 7-9, 11-14, 16-18, 20-28, and 33-37 have been amended to correct the dependencies of these claims with respect to the newly added claims. Claim 5 has been amended to read, in part, "... the monoacyl phospholipid or the diacyl phospholipid are obtained by enzyme digestion of lecithin." Claim 11 is amended to include more conventional Markush group language. Claim 14 is amended to include more conventional Markush group language and by deleting "another." Applicants also amended claims 6, 16 and 17 by replacing "lipid" with --phospholipid--. To be consistent with new claims 39 and 40, Applicants have amended claims 5-25 by replacing "composition" with --polymer associate--. Claim 31 has been amended to read, in part, "... a biologically active compound and at least one of a monoacyl and a diacyl phospholipid ... ." Claim 32 has been amended to read, in part, "... wherein the polymer is a natural polysaccharide polymer." Claim 32 has also been amended by replacing "lipids" with --phospholipids--. Similarly, claims 33-37 have been amended by replacing "lipid" with --phospholipid--. Also, new claims 39-46 have been added to further define preferred embodiments of the present invention. Support for new claims 39-41 can be found at least at original claim 1. Support for new claims 43 and 44 can be found at least at original claim 26. Support for

new claims 42 and 46 can be found at least at page 5, paragraphs 1-3 and in the Examples. In addition, support for new claims 39 and 43 can be found in Examples 6-17. New claims 40, 41, 44 and 45 are also supported by Examples 31-36 together with the disclosure at page 15, lines 10-11. Additionally, new claims 42 and 46 are supported at least by the disclosure at page 5, lines 8-11. New claim 47 is supported at least by original claim 32.

Turning now to the Official Action, the specification stands objected to for failing to include a Brief Description of the Drawings. Applicants have amended the specification to obviate this rejection. In particular, Applicants have amended the specification at page 6, by adding a Brief Description of the Drawings.

Accordingly, reconsideration and withdrawal of the objection are in order.

Claims 1-38 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. For at least the reasons that follow, withdrawal of the rejection is in order.

With respect to the rejection of claim 1, Applicants submit that the rejection is now moot as claim 1 has been canceled and replaced with new claims 39 and 40. Further, Applicants submit that new claims 39 and 40 overcome the rejection that was made with respect to claim 1.

With respect to the rejection of claims 2 and 32, Applicants submit that the rejection of claim 2 is now moot as claim 2 has been canceled. Additionally, with respect to claim 32, Applicants submit that "GRAS" stands for "generally regarded as safe." Applicants further submit that this expression is commonly used by those of ordinary skill in the art such as, for example, by the U.S. F.D.A. to describe the very low toxicity of substances.

Accordingly, Applicants submit that because the above term is readily understood by those of ordinary skill in the art, it is unnecessary to amend claim 32 to obviate the rejection.

With respect to the rejection of claims 3 and 4, Applicants submit that the rejection is now moot as claims 3 and 4 have been canceled.

With respect to the rejection of claim 5, Applicants have amended claim 5 to obviate the rejection. In particular, Applicants have amended claim 5 to indicate that the "monoacyl and diacyl" phospholipids are obtained by enzyme digestion of lecithin.

With respect to the rejection of claim 11, Applicants have amended the claim to obviate the rejection. In particular, Applicants have amended claim 11 to include more conventional Markush group language.

With respect to the rejection of claim 14, Applicants have amended the claim to obviate the rejection. In particular, Applicants have amended claim 14 to include more conventional Markush group language and by deleting the word "another."

With respect to the rejection of claim 27, Applicants have amended the claim to obviate the rejection. In particular, Applicants have amended the claim to read in part "...wherein the lipid and biologically active compound, if present, are dissolved...."

With respect to the rejection of claim 29, Applicants have amended the claim to obviate the rejection. In particular, Applicants have corrected the spelling of the word "said."

With respect to the rejection of claim 32, Applicants have amended the claim to obviate the rejection. In particular, Applicants have amended claim 32 to read in part "...wherein the polymer is a natural polysaccharide polymer." In addition, Applicants have

added new claim 45, which further defines the natural polysaccharide polymer as being selected from the group consisting of a starch, a starch derivative, a cellulose, a cellulose derivative and a cellulose gelatin.

With respect to the rejection of claim 36, for use of the term "partially synthetic," Applicants provide the following remarks. Applicants submit that the term "partially synthetic" is commonly used by those of ordinary skill in the art to refer to substances which are obtained from natural sources which are modified synthetically. Thus, Applicants submit that claim 36 does not need to be amended to obviate the outstanding rejection. If, however, the Examiner believes that the subject matter of claim 36 is encompassed by claim 37, Applicants may be willing to consider canceling claim 36.

For at least these reasons, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, are requested.

Claims 1-3, 7-17, 33-34 and 36-38 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ke (U.S. Patent No. 5,221,696). For at least the reasons that follow, withdrawal of the rejection is in order.

Exemplary embodiments of the present invention relate to the preparation of powder or solid compositions comprising single and double chain amphiphilic lipids generally. Lipid compositions comprising monoacyl and diacyl membrane lipids are associated with polymers and biologically active compounds for administration to a living organism. Lipid polymer compositions can be produced which have improved physical characteristics and higher loading capacity for lipophilic and hydrophilic compounds. Stable membrane lipid compositions in particulate and in compact forms can be produced with superior

bioavailability, suitable for oral and other applications. See specification at page 1, lines 5-15.

For example, new claim 39 defines a phospholipid polymer associate prepared by removing an organic solvent or an organic solvent and water from a homogeneous dispersion or solution comprising at least one of a monoacyl phospholipid and a diacyl phospholipid; a polymeric material; and an organic solvent or a mixture of an organic solvent and water, said phospholipid polymer associate being of particulate form.

Additionally, new claim 40 defines a phospholipid polymer associate prepared by removing water from a homogeneous dispersion comprising at least one of a monoacyl phospholipid and a diacyl phospholipid; a natural polysaccharide polymer and water, said phospholipid polymer associate being of particulate form.

It is well established that in order to demonstrate anticipation under § 102(b), each element of the claim in issue must be found, either expressly described or under principles of inherency, in a single prior art reference. See Kalman v. Kimberly-Clark Corp., 218 USPQ 789 (Fed. Cir. 1983). That is not the case here.

In particular, Ke fails to disclose or suggest compounds that are in particulate form, as claimed. Instead, Ke is concerned with liquid or gel-like formulations for ophthalmic applications. See Ke, for example, at col. 4, lines 7-10, which states "the monoacyl phosphoglycerides can be formulated in compositions which are solutions, suspensions, ointments, gels or films." Even though Ke may disclose using viscosity enhancing polymers, nowhere does Ke disclose or fairly suggest a particulate phospholipid polymer

associate prepared using a dispersion or solution as defined, for example, in independent claims 39 and 40.

For at least these reasons, claims 39 and 40 are not anticipated by Ke. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-4, 8-9, 12, 14-18, 26-29 and 31-37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0181287 (EP '287). For at least the reasons that follow, withdrawal of the rejection is in order.

EP '287 fails to disclose or fairly suggest each element of the presently claimed invention, either expressly or under the principles of inherency.

For example, EP '287 is directed to lyophilised dry-powders which are prepared by lyophilisation of aqueous solutions (see, for example, claim 7) and which are suitable for preparing stable aqueous suspensions for injections. EP '287 discloses adding a polyethylene glycol only in combination with aqueous solvents. Accordingly, Applicants submit that EP '287 fails to anticipate the polymer associates or methods of preparing polymer associates of the presently claimed invention defined, for example, in claims 39 and 43. That is, EP '287 fails to disclose or suggest a particulate phospholipid polymer associate prepared with the homogeneous dispersion or solution of claims 39 and 43. Also, as EP '287 fails to disclose or fairly suggest the specific polymers defined in claims 40, 41, 44 and 45, Applicants submit that the subject matter of these claims also is not anticipated by EP '287.

For at least these reasons, claims 39, 40, 41, 43, 44 and 45 are not anticipated by EP '287. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-5, 9-10, 12-18, 26-31 and 33-37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by EPA0635218 (EP '218). For at least the reasons that follow, withdrawal of the rejection is in order.

EP '218 fails to disclose or fairly suggest each element of the presently claimed invention, either expressly or under principles of inherency.

For example, EP '218 teaches a protein-lipid complex for decreasing the bitterness of foods, pharmaceuticals and cosmetics. EP '218 does not, however, disclose a particulate phospholipid polymer associate prepared with the homogeneous dispersion or solution of claims 39 and 43. That is, nowhere does EP '218 disclose or fairly suggest a dispersion or solution comprising at least one of a monoacyl phospholipid and a diacyl phospholipid, a polymeric material and an organic solvent or a mixture of an organic solvent and water. To the contrary, EP '218 discloses at page 2, lines 15-19 that the protein-lipid complex is prepared using water. Additionally, nowhere does EP '218 specifically disclose or suggest the polymers defined in claims 40, 41, 43 and 44.

For at least these reasons, claims 39, 40, 41, 43 and 44 are not anticipated by EP '218. Accordingly, reconsideration and withdrawal of the rejection are requested.

Claims 1-4, 8-9, 11-12, 14-19, 23-29 and 31-38 stand rejected under 35 U.S.C. § 102(b) as being anticipated by DE-A-195 31 277 (DE '277). For at least the reasons that follow, withdrawal of the rejection is in order.

DE '277 fails to disclose or fairly suggest each element of the presently claimed invention, either expressly or under principles of inherency.

For example, DE '277 discloses using lipids for the preparation of solid pharmaceutical compositions in a melt extrusion process. The lipids are used as mold release agents and lubricants. See, for example, DE '277 at page 2, lines 54-55. DE '277 is, however, silent with respect to a particulate phospholipid polymer associate, useful as a carrier for a biologically active compound. Furthermore, DE '277 fails to disclose or fairly suggest a particulate phospholipid polymer associate prepared with a dispersion or solution comprising at least one of a monoacyl phospholipid and a diacyl phospholipid, a polymeric material and an organic solvent or a mixture of an organic solvent and water. See claims 39 and 43.

For at least these reasons, claims 39 and 43 are not anticipated by DE '277. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

With respect to the Examiner's comment that the rejection will be reconsidered in view of the English language translation of DE '277, Applicants have enclosed herewith a copy of the Canadian equivalent of DE '277, Canadian Patent No. 2,227,272, which is in the English language, except for the initial page.

Claims 1-5, 7-12, 14-15, 26-28 and 31-38 stand rejected under 35 U.S.C. § 102(b) as being anticipated by JP06-245719 (JP '719). For at least the reasons that follow, withdrawal of the rejection is in order.

JP '719 fails to disclose or fairly suggest each element of the present invention, either expressly or under principles of inherency.

For example, JP '719 is directed to the spray drying of water in oil emulsions. See JP '719 at Abstract. Further, while the Abstract may mention lecithin, JP '719 fails to disclose or fairly suggest a particulate phospholipid polymer associate prepared with a homogeneous dispersion or solution comprising at least one of a monoacyl phospholipid and a diacyl phospholipid, a polymeric material, and an organic solvent or a mixture of an organic solvent and water, as claimed in claims 39 and 43.

For at least these reasons, claims 39 and 43 are not anticipated by JP '719. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-3, 7-17, 33-34 and 36-38 stand rejected under 35 U.S.C. §102(b) as being anticipated by Leigh (U.S. Patent No. 5,141,674). For at least the reasons that follow, withdrawal of the rejection is in order.

Leigh fails to disclose or fairly suggest each element of the presently claimed invention, either expressly or under principles of inherency.

For example, Leigh discloses sprayable compositions that contain a lipid and a biologically active compound in the form of a micronized powder. Leigh does not disclose or fairly suggest a phospholipid polymer associate prepared with a homogeneous dispersion or solution comprising at least one of a monoacyl phospholipid and a diacyl phospholipid, a polymeric material and an organic solvent or a mixture of an organic solvent and water. See claims 39 and 43. In column 4, lines 16-17, for example, Leigh requires that "the solid carrier must not be soluble in the solvent" (for the lipid). Accordingly, Applicants submit that Leigh actually teaches away from the presently claimed invention.

In addition, Leigh discloses that the "lipid is first dissolved in a volatile solvent which is not a solvent for the drug." See also column 4, lines 8-10 of Leigh. Accordingly, Applicants submit that Leigh is actually directed to an entirely different composition. That is, contrary to the claimed invention, the drug and polymer of Leigh must not be soluble in the (organic) solvent for the lipid. Thus, Leigh actually teaches away from forming a co-solution or co-dispersion.

Additionally, among other lipids, Leigh discloses liposomes which are made from lecithin. Applicants submit that it is well known that lecithins are known to contain only very small amounts of lyso-impurities. See, for example, U.S. Patent No. 6,303,803, which the Official Action itself cites, at column 7, lines 8-15, which specifies: "a typical composition of soy lecithin contains (all per 100g) 73g of phospholipids (23g PC, 20 gPE, 14gPI, 7gPA, and 9g of other phospholipids such as acylphosphatidylethanolamine, diphosphatidylglycerol, lysophosphatidylethanolamine, and lysophosphatidylcholine), 15g of glycolipids, 9g of carbohydrates and moisture, and 3g of neutral lipids (e.g., triacylglycerols, free fatty acids, diacylglycerols, and monoacylglycerols)." From this disclosure, which the Official Action itself relies upon, it is apparent that in lecithin the lyso components are only a minor impurity. Thus, for at least these reasons, the further rejections of the subject matter defined in dependent claims 2, 3, 7-17, 33-34 and 36-38 are improper and should be withdrawn.

For at least these reasons, the presently claimed invention is not anticipated by Leigh. Accordingly, reconsideration and withdrawal of the rejection are in order.

Claims 6 and 16-25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over EP '218. For at least the reasons that follow, withdrawal of the rejection is in order.

For at least all of the reasons set forth above with respect to the §102(b) rejection over EP '218, Applicants submit that claims 39-44, would not have been obvious over EP '218. Accordingly, EP '218 also fails to render obvious claims 6 and 16-25, which depend directly or indirectly from claims 39-44. In particular, EP '218 fails to disclose or fairly suggest any specific amount of monoacylphosphilids let alone the specific mole percent amount defined in claim 6. Further, as the Official Action admits, EP '218 also fails to disclose or fairly suggest using any specific drug or specific particle size, let alone the specific drugs and particle sizes defined in dependent claims 16-25. Furthermore, while the Official Action asserts that "it would have been obvious to one of ordinary skill in the art that the granules can be of any sizes" and that "it is deemed obvious to use any drug in EP '218 with a reasonable expectation of success," Applicants note that the Official Action fails to provide any evidence to support this assertion. Absent any supporting evidence, Applicants submit that the rejection is improper and should be withdrawn.

For at least these reasons, claims 6 and 16-25 would not have been obvious over EP '218. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-28 and 31-38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Leigh in view of Huang (U.S. Patent No. 5,043,164) and Baumann (U.S. Patent No. 5,009,956) alone or in combination. For at least the reasons that follow, withdrawal of the rejection is in order.

For at least all of the reasons set forth above with respect to the §102(b) rejection over Leigh, Applicants submit that the presently claimed invention would not have been obvious over Leigh, either alone or in combination with the cited secondary references. In particular, Applicants submit that, as explained above, Leigh discloses among other lipids liposomes, which are made from lecithin. Again, Applicants submit that it is well known that lecithins contain only very small amounts of lyso-impurities. See for example, U.S. Patent No. 6,303,803, which the Official Action itself cites in support of it rejection over Leigh. Additionally, nowhere does Leigh disclose or fairly suggest using enzyme digested lecithins.

Huang and Baumann fail to overcome the deficiencies of Leigh. In particular, Huang discloses that the addition of lysolecithins to DOPE/fatty acids lyposomes may increase the physical stability (i.e., size, shape, structure) of lyposomes. The same applies to Baumann, which discloses using lysophospholipids in order to stabilize lyposomes physically and inhibit the degradation or cleavage of lyposomes by phospholipase A_2, which is present in the bloodstream.

The claimed invention, however, is not concerned with the formation of liposomes. In particular, the type of lipid structures formed depends on the nature of the active compound and/or the choice of the lipid used or the extent of dilution, diluting medium and the presence of other components. Thus, the composition can result in the formation of one or more types of other lipid structures such as micelles or mixed micelles.

The invention of claims 39-44 is directed to a particulate phospholipid polymer associate prepared from a homogeneous dispersion or solution. In stark contrast, neither

Huang nor Baumann disclose or fairly suggest a polymer associate prepared from a homogeneous dispersion or solution comprising at least one of a monoacyl phospholipid and a diacyl phospholipid, a polymeric material and an organic solvent or a mixture of an organic solvent and water. See claims 39 and 43. Accordingly, Applicants submit that neither Huang nor Baumann when combined with Leigh would enable one to arrive at the presently claimed invention.

With respect to the Official Action's statement that the priority document UK 99827006.9 has not been received, Applicants wish to point out that PCT Rule 17.2 does not require applicants to provide a copy of the priority document. Nevertheless, in an effort to expedite prosecution of the instant application, a copy of the requested priority document is enclosed herewith for the Examiner's convenience.

For at least the above reasons, Applicants submit that the presently claimed invention would not have been obvious over Leigh, Huang or Baumann, either alone or in combination. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

From the foregoing, Applicants earnestly solicit further and favorable action in the form of a Notice of Allowance.

If there are any questions concerning this paper or the application in general,

Applicants invite the Examiner to telephone the undersigned at his earliest convenience.

Respectfully submitted,

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Date: January 27, 2003

Attachments: U.S. Patent No. 5,002,940 (equivalent to EP-0181287)
CA-A-2,227,272 (equivalent to DE-A-19531277)
UK 9827006.9 (priority document downloaded from corresponding EP file)

Attachment to Amendment dated January 27, 2003

Marked-up Claims 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29, 33, 34, 35, 36 and 37

5. (Amended) The [composition] polymer associate of claim [1 or 2,] 39 or 40 [comprising an enzyme digested], wherein the monoacyl phospholipid or the diacyl phospholipid are obtained by enzyme digestion of lecithin.

6. (Amended) The [composition] polymer associate of claim 5, comprising 60-80 mol % of monoacyl [lipid] phospholipid.

7. (Twice Amended) The [composition] polymer associate of claim [1] 39, wherein the polymeric material comprises a natural gum or a derivative thereof.

8. (Twice Amended) The [composition] polymer associate of claim [1] 39, wherein the polymeric material comprises a synthetic polymer.

9. (Twice Amended) The [composition] polymer associate of claim [1] 39, wherein the polymeric material [has] comprises cationic or anionic groups.

10. (Twice Amended) The [composition] polymer associate of claim 9, wherein the polymeric material has carboxyl or sulfate ester groups.

Attachment to Amendment dated January 27, 2003

Marked-up Claims 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29, 33, 34, 35, 36 and 37

11. (Twice Amended) The [composition] polymer associate of claim [1] 39, wherein the polymeric material is selected from the group consisting of a salt of carboxymethylcellulose, aliginic acid, [or] a salt [thereof] of aliginic acid, a starch modified with anionic groups, agar, carrageenan, gum arabic, gum tragacanth, gum xanthan, pectin, carboxypolymethylene, a methyl vinyl ether/maleic acid copolymer, an [and] ammonio methacrylate copolymer, chitosan, a methacrylic acid copolymer, and a hydrolysed gelatin.

12. (Twice Amended) The [composition] polymer associate of [claim 1] claims 39 or 40, wherein [there is present at least 10 wt.% of] the polymeric material is present in an amount of at least 10 wt.% based on the weight of [said base] the composition.

13. (Twice Amended) The [composition] polymer associate of claim [1] 39, further comprising a sugar.

14. (Twice Amended) The [composition] polymer associate of claim [1] 39, further comprising a member selected from the group consisting of a polyol, a sucrose ester, [or] a polyglyceryl ester, [or] a higher fatty acid, [or another] and a polyol ester of a higher fatty acid.

Attachment to Amendment dated January 27, 2003

Marked-up Claims 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29, 33, 34, 35, 36 and 37

16. (Amended) The [composition] polymer associate of claim [15] 41, wherein the ratio by weight of the [lipid] phospholipid to the active compound is from 40:1 to 1:40.

17. (Amended) The [composition] polymer associate of claim [15 or 16] 41, wherein the active compound is present in molecular dispersion in the [lipid] phospholipid.

18. (Amended) The [composition] polymer associate of claim [15 or 16] 41, wherein the active compound is present as discrete particles in the composition.

19. (Amended) The [composition] polymer associate of claim 18, wherein the size of said particles is not more than 1 μm.

20. (Twice Amended) The [composition] polymer associate of claim [1] 41, wherein the biologically active compound is cyclosporin A, Taxol, tacrolimus or a rampamycin.

21. (Twice Amended) The [composition] polymer associate of claim [1] 41, wherein the biologically active compound is insulin, calcitonin or heparin.

Attachment to Amendment dated January 27, 2003

Marked-up Claims 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29, 33, 34, 35, 36 and 37

22. (Twice Amended) The [composition] polymer associate of claim [1] 41, wherein the biologically active compound is ubiquinone, tocopherol, carotenoid or a bioflavenoid.

23. (Twice Amended) The [composition] polymer associate of [1] 41, which is of powder of size 50-2000μm.

24. (Twice Amended) The [composition] polymer associate of [1] 41, which is of powder of size 50-1000μm.

25. (Twice Amended) The [composition] polymer associate of claim [1] 41, which is of a granules of size 1-5 μm.

27. (Amended) The method of claim [26] 44, wherein the lipid and biologically active compound, if present, [(if present)] are dissolved in ethanol, the polymer is dissolved in water, the aqueous and ethanolic solutions are mixed, and the mixture is dried.

28. (Amended) The method of claim [26 or] 27, comprising the further step of comminuting the composition after the solvent has been removed.

Attachment to Amendment dated January 27, 2003

Marked-up Claims 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29, 33, 34, 35, 36 and 37

29. (Amended) The method of claim 28, comprising the further step of forming [siad] said comminuted composition into a tablet.

33. (Amended) The composition of claim [1] 39 or 31, wherein the [lipid] phospholipid comprises a natural lipid.

34. (Amended) The composition of claim [1] 39 or 31, wherein the [lipid] phospholipid is an enzyme modified natural lipid.

35. (Twice Amended) The composition of claim [1] 39 or 31, wherein the lipid is derived from egg or soya.

36. (Amended) The composition of claim [1] 39 or 31, wherein the [lipid] phospholipid comprises a partly synthetic lipid.

37. (Amended) The composition of claim [1] 39 or 31, wherein the [lipid] phospholipid comprises a synthetic lipid.